

Molecular Imaging with Ga-68 DOTATATE PET to Investigate Neuroendocrine Differentiation in Prostate Cancer Patients

NCT03448458

Informed consent date: Nov 7th, 2019



You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.



Emory University Consent to be a Research Subject / HIPAA Authorization

Title: Molecular Imaging with Ga-68 DOTATATE PET to Investigate Neuroendocrine Differentiation in Prostate Cancer Patients

Investigator-Sponsor: Mehmet Asim Bilen, MD and Ephraim Parent, MD, PhD

Study-Supporter: Emory Department of Radiology & Imaging Sciences Winship Cancer Institute of Emory University

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?

The purpose of this study is to evaluate a new imaging test for men with prostate cancer that has progressed while on androgen deprivation therapy. The test might be able to identify

patients with early neuroendocrine transdifferentiation, which can develop into a more aggressive form of prostate cancer.

The imaging agent that will be tested is called ^{68}Ga -DOTATATE, which is combined with positron emission tomography (PET) CT scanning. Neuroendocrine tumors have high levels of proteins called somatostatin receptors. Some studies have suggested that agents similar to somatostatin (such as ^{68}Ga -DOTATATE) can bind to these receptors and enter tumors, and may therefore be useful in detecting neuroendocrine tumors using imaging tests such as PET-CT scans.

^{68}Ga -DOTATATE will be injected into a vein in your arm, then scans (“pictures”) are taken using the PET scans. These pictures will allow the doctor to see the inside of your body. ^{68}Ga -DOTATATE has been approved by the FDA (Food and Drug Administration) for PET/CT imaging of patients with somatostatin receptor positive neuroendocrine tumors.

Here at Emory, we planned to enroll twenty (20) patients in this study. The treating physician will identify patients who are eligible for this study. These are patients whose prostate cancer has been treated with androgen deprivation and is not responding to the treatment (“castration-resistant”).

What will I be asked to do?

All patients who are enrolled in this study will have a ^{68}Ga -DOTATATE PET/CT scan followed by standard of care treatment and imaging.

Screening:

- Your physician will review your medical charts to see if you are eligible to take part in the study. If you are eligible, the physician will discuss the study with you and you will be given time to review this consent form and ask questions.

Day 1:

- If you are eligible to take part in the study, you will be asked to sign consent.
- You will be asked about your medical history
- The ^{68}Ga -DOTATATE PET/CT scan will be performed. An intravenous tube called a catheter (IV) will be put in a vein in your arm to be used later for injection of the ^{68}Ga -DOTATATE

^{68}Ga -DOTATATE PET-CT scan:

The PET-CT scans are done in the Nuclear Medicine Department on the first floor of the Emory University Hospital or in the Winship Cancer Institute. The entire procedure takes about 2 hours, including set up and preparation time. You are not required to fast before the PET-CT scan and are encouraged to drink water before and after administration of ^{68}Ga -DOTATATE with frequent voiding. One hour prior to scanning, you will drink one glass (450 ml) of oral contrast to allow for better pictures of your abdomen and pelvic organs

The scanner has the appearance of a large box. You will be asked to lie on a scanning bed, the bed will move slowly through the PET/CT scanner. The CT portion of the exam sends X-rays through the body that is then measured by detectors in the CT scanner. This portion usually takes about one minute. Following this, you will receive the FACBC by injection into the IV and the PET scan portion of the exam will begin. The PET scanner has cameras that detect the gamma rays emitted from the patient, and turns those into electrical signals. A computer processes these to generate the images. The table moves slowly through the scanner and many sets of PET-CT images are produced.

When the imaging is complete, the scanner will send the results to a computer. The computer then generates a number of images that will be reviewed by a specially trained radiologist. Once the procedure is finished, the IV needle is removed and you will be able to leave the PET Center after this time.

Standard of care evaluation

Note that you will undergo typical evaluation by your doctor for at least 1 year following the ⁶⁸Ga-DOTATATE. PET/CT. These follow up includes blood tests such as PSA, and routine imaging such as bone scan, CT, or MRI of the body.

Follow-Up

Follow-up phone call will be made to patient one week after each PET scan to assess for any ill effects.

All patients will be followed for at least one (1) year. We will look at your medical records to see your PSA results and the results of any scans.

Who owns my study information and samples?

You will not receive any compensation for your information to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the imaging agent that are not known at this time.

Everyone taking part in the study will be watched carefully for any side effects. However, researchers do not know all the side effects that may happen. Side effects may be mild or very serious. The procedures described in this study may cause all, some, or none of the side effects listed here. These common procedures are considered relatively safe. Previously unknown side effects can also occur. If new side effects are reported, you will be told. It is also important that you give us accurate and complete information about your past medical history.

You may also find it uncomfortable to lie without moving during the approximately 45 minutes necessary to complete the scan. If you believe you cannot lie still for 45 minutes, you should not take part in this study.

Although the risk is small, it is possible to develop an allergic reaction to the Ga-68 DOTATATE. This can result in hives, rash, itching, and difficulty breathing which may require emergency medical treatment. In three single center studies that used Ga-68 DOTATATE PET to image neuroendocrine tumors, no adverse effects were reported; however, it is important to report to your doctor, any unusual side effects that you are having such as itching, flushing, pain or rash spreading up your arm, hives or swelling of your lips, tongue or face, fever, chills, nausea, dizziness, and vomiting.

There is always the risk that the test result incorrectly shows that the condition exists (false positive).

Intravenous Catheter:

When the IV is placed or removed, the site of insertion may become sore or bruised. Rarely, bleeding or infection can occur at this site; however, this is highly unlikely. A small gauze pad or bandage is placed over the site after the IV catheter is removed.

Radiation Safety:

You will be exposed to radiation from nuclear medicine and CT scans. Some of these procedures are not necessary for your medical care and will occur because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal.

Will I benefit directly from the study? We do not know that the information from this study will help researchers learn more about how best to treat men who are receiving treatment for prostate cancer, but are trying to find something out in this Pilot trial which may also find nothing.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. The study doctor will discuss these with you.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Bilen at 404-778-1900. You should also let any health care provider who treats you know that you are in a research study.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment for your injury or illness that the sponsor does not pay. Your insurer may be told that you are in a research study. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will not be charged for the Ga-68 DOTATATE PET scan, The Sponsors will pay for this scan.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will **not** pay for your regular medical care including bone scans, MRI or CT scans that will be done to see if you are responding to the treatment. Any other care you receive related to your prostate problem.

If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory I may use and disclose your PHI to get payment for study related treatment and to run normal business operations. The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Mehmet Asim Bilen, MD and Ephraim Patent, MD, PhD is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done

correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
 - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
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 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. Mehmet Asim Bilen
1365 Clifton Road NE
Atlanta, GA 30322
404-778-1900

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

**Signature of Person Conducting Informed
Consent Discussion**

Date

**____:____ am / pm
Time (please circle)**